

REMARKS

Claims 5-7, 9, 12-15, 33-34, 40, 44-54, 59-62, and 79-83 are pending.

Claims 8, 42, 43, 55-58, 85 and 87-99 have been withdrawn.

Claims 1-4, 10-11, 16-32, 35-39, 41, 63-78, 84 and 86 are cancelled.

Support for the above amendments are as follows:

Support for the amendment to claim 5 is found in the paragraph bridging pages 4 and 5; page 14, line 13, and at page 19, lines 5-10.

Support for the amendment to claim 6 is found at page 14, line 19.

Support for the amendment to claim 7 is found in the paragraph bridging pages 4 and 5; and at page 19, lines 5-10.

Support for the amendment to claim 9 is found in the paragraph bridging pages 4 and 5; and at page 19, lines 5-10, and at page 20, lines 8-12.

Support for the amendments to claims 33 and 34 is found in the paragraph bridging pages 4 and 5.

Support for the amendment to claim 40 is found at page 20, lines 8-12.

Support for the amendment to claim 47 is found in the paragraph bridging pages 5 and 6; at page 23, lines 14-19; at page 16, line 20 to page 17, line 20; at page 24, line 3 and at page 23, lines 21-22.

Support for the amendment to claim 59 is found at page 24, line 7 to page 5, line 3.

Support for the amendment to claim 79 is found at page 24, lines 19- 25; page 13, line 26 to page 14, line 3; page 24, line 7 and page 5, line 3.

Applicants are appreciative of the Examiner's indication of allowability of claim 54.

In the above-noted Office Action, the Examiner found that claims 55-58 to be directed to non-elected embodiments and withdrew those claims.

Applicants respectfully traverse the above withdrawal. In response to the election of species requirement for Group I, Applicant elected Species IC (Dispenser with Lever Mechanism 41 and spring-loaded reservoir); the embodiment of Figures 4-6 for prosecution on the merits. Claims 55-58 appear to be readable upon a Dispenser with a Lever Mechanism and a spring-loaded reservoir. See, for example, FIG. 9A.

The Examiner also requested that Applicant's change of inventorship request be provided on a separate paper. Applicants have done so and have included that paper with this filing.

Claims 6 and 65-67 stand rejected under 35 USC 112, second paragraph for indefiniteness.

In claim 6, the Examiner has taken the position that the recitation of an angle of 30 degrees contradicts the parent claims of substantially linear. Applicants have amended this claim to recite a flowpath having an angle of less than 45 degrees.

In claims 65-67, the Examiner has taken the position that there is no antecedent basis for "the integral means". Applicants have amended these claims to remove the word "integral".

Claims 1-6 9-31, 35, 36 38-41, 44-53, 59-61, 63, 68-81, 84, and 100 stand rejected under 35 USC 103, as being unpatentable over Tolson (USP 6,217,581) in view of Scales (4,405,249) and Jacques (USP 1,894,274).

Claims 1-6 9-41, 44-53, 59-81, 84, and 100 further stand rejected under 35 USC 103, as being unpatentable over Tolson (USP 6,217,581) in view of Scales (4,405,249) and Stamper (USP 1,894,274).

Claims 1-6 9-31, 35, 36 38-41, 44-53, 59-61, 63, 68-81, 84, and 100 stand rejected under 35 USC 103, as being unpatentable over Tolson (USP 6,217,581) in view of Scales

(4,405,249) and Jacques (USP 1,894,274), as applied above with respect to these claims and further in view of Phillips (USP 4,717,383)(piston with O-ring); Draenert (USP 4,671,263)(O-ring); and Hauke (USP 5,551,778 (seal).

In each of these rejections, the Examiner takes the position that it would have been obvious to one of ordinary skill in the art to have used a sterilized prior art lubricating gun as the high pressure gun 20 disclosed by Tolson in light of Tolson's Figures showing a very similar gun and disclosure that the gun may be those typically found in the automotive lubricating industry.

In light of the cited art, Applicants have amended the claims of the present invention.

Amended claims 5 and 6 recite a substantially linear flowpath having an angle of less than 45 degrees. Neither Jacques nor Stamper disclose a substantially linear flowpath. In particular, each of Jacques and Stamper disclose flowpaths having an angle of about 90 degrees. Although the 90 degree angle provided in these cited devices (and apparently in the FIG. 1 device of Tolson as well) may easily deliver low viscosity lubricants, the extreme angle present in these cited devices produces a tortuous exit path that is not conducive to easily delivering a high viscosity bone cements. Therefore, medical procedures that deliver high viscosity cement through such high-angle devices would be prone to failure. See page 14, lines 4-10 of the as-filed application.

In contrast, the more linear nature of the flowpath of the present invention is not so tortuous and so provides an advantage over the cited art by allowing high viscosity bone cement to flow therethrough with relative ease. Accordingly, the device of the present invention having a flowpath angle of less than 45 degrees is less prone to failure. In addition, the claimed device having a flowpath of less than 45 degrees is much easier to mold than the 90 degree flowpaths of the cited art devices.

Since there is no recognition in any of the cited references that a 90 degree flowpath would be tortuous for high viscosity fluids, nor any teaching or suggestion that

modifying the flowpaths of the cited devices to have an angle of less than 45 degrees would be advantageous in any respect, the present rejection should be withdrawn.

Amended claim 7 recites an O-ring disposed between the sidewall of the first piston (in the injection chamber) and the inner surface of the injection chamber. Neither Jacques nor Stamper disclose an O-ring in their respective injection chambers, nor does either provide any motivation for making such a modification. Although each of Draenert, Phillips and Hauke disclose O-rings within their devices, Applicant submits that there is no teaching or suggestion in the secondary references to combine these secondary references with the cited primary references in the manner sought to arrive at an O-ring within the injection chamber.

Respecting Draenert, although Draenert discloses a scaling ring in its single chamber, the problem confronted by Draenert related essentially to eliminating air present in a single chamber during mixing (i.e., when the chamber is acting as a mixing chamber). It appears that the purpose of the Draenert seal relates to directing air out of the cement during mixing. Because the seal relates to a mixing chamber function, the skilled artisan reading Draenert would have no motivation to provide a seal upon a piston in the injection chamber portion of a dual chamber device. In fact, Draenert teaches away from such a modification. In particular, Draenert specifically notes that in simple syringe-type designs, sealing the piston is specifically discouraged:

With the commercial syringes which in part comprise a one-way cartridge and a simple manually operated piston, it is possible to render the bone cement somewhat more compact. The piston must not tightly seal the cylinder holding the bone cement in order that the air above the cement is not pressed into the cement (col. 2, lines 57-62)

Respecting Phillips, the O-ring is merely disclosed in a single chamber device without any discussion of its purpose. Because Phillips does not provide any reason for providing an O-ring, Phillips can not provide any motivation for modifying the primary references with an O-ring.

Respecting Hauke, the problem confronted by Hauke related to sealing the liquid and powder components of the cement in a chamber during mixing. See col. 1, lines 60-66. The reason for the provision of a seal on the discharge plunger 12 appears to relate the fact that the liquid monomer 15 sits upon the plunger. See FIG. 2. In this respect, the skilled artisan would not have any motivation for providing a seal upon the piston of an injection chamber in a dual chamber device (as the cement would be mixed in the reservoir, if at all). Accordingly, the present rejection should be withdrawn.

Amended claim 9 recites a device capable of providing an injection of a discrete quantity of bone cement in a volume of between 0.1 cc and 0.5 cc. Injection volumes within the claimed range are advantageous because they provide the clinician with increased control over the amount of cement deposited within a vertebral body during a single stroke. With small volumes, there is less danger that the injected amount from a single stroke would leak outside the fractured vertebral body. This is important because clinicians often inject a single stroke of bone cement (while in the X-ray field) without the aid of fluoroscopy, then move outside the X-ray field and turn on X-ray field to view the results of the injected stroke. In this regard, Applicants note that the smallest injection volume disclosed Jensen, AJNR: 18 Nov. 1997 (at 1899) is 1 cc. Since none of the cited prior art recites a particular injection volume (much less such a small injection volume as the cited range), nor even an appreciation that injecting very small amounts would be favored, the present rejection should be withdrawn.

Amended claim 14 recites a sealing connection between the sidewall of the first piston and the inner surface of the injection chamber. This claim is patentable for the same reasons as claim 7, provided above.

Amended claim 33 recites a device wherein the piston of the first injection chamber operates as a check valve, thereby advantageously eliminating the need for an additional component. In contrast, Stamper discloses providing a freely moveable ball housed in the injection chamber that closes the conduit between the reservoir and injection chamber when pressure in the injection chamber rises. Since Stamper

emphasizes the utility of the freely moveable ball in solving the problem confronted, and does not disclose the use of the piston as a check valve, there is no teaching or suggestion in Stamper to modify the ball-containing check valve to include the piston as a check valve, and the present invention should be withdrawn.

Amended claim 34 recites a flow restrictor within the injection chamber, wherein the flow restrictor comprises a slitted sheet disposed parallel to inner face of the first piston, the sheet comprising flaps formed by slits and configured to restrict backflow. The Examiner took the position that Stamper discloses a check valve 48 having a slitted sheet 52. Applicants respectfully traverse.

Stampers does not disclose a flow restrictor disposed parallel to the inner face of the first piston. Rather, Stampers discloses a check valve 48 having a resilient disc 49 in which there is disposed a plurality of openings 52. As noted by Stamper at col. 3, line 34, the response of this check valve 48 to increased pressure is shown in FIG. 3 of Stamper. Simply, the entire check valve 48 moves distally and then flexes distally in response to such increased pressure. The resilient disc of Stampers has permanent channels axially disposed therethrough. Accordingly, the flexing of this component does not create a through-channel from the proximal side of the disc to the distal side (as the through-channel is already there).

In contrast, the present claim requires a slitted sheet comprising flaps formed by slits. When pressure is generated by distal movement of the first piston, the flexible flaps open distally and create a channel through the sheet to provide an avenue for passage of the cement. The flexing of this component does create a through channel through the component from the proximal to the distal side. The advantage of providing a flow restrictor comprising a slitted sheet comprising flaps formed by slits is discussed at page 15, lines 15-23 of the as-filed application. Since Stamper does not create a channel through its resilient disc during operation, and the resilient disc appears to be a primary feature of the Stamper device, the skilled artisan would not be motivated by Stamper to modify Stamper's resilient disc to provide flaps that open distally and create a channel through the disc. Accordingly, the present invention should be withdrawn.

Amended claim 40 recites a small 0.1-0.5 cc injection volume, and so is patentable for the reasons provided above in the discussion of amended claim 10.

Amended claim 47 recites a handle means for locking the second piston at a predetermined location comprising a rod that is both axially retractable and axially fixable.

Respecting Jacques, it appears that the Jacques device differs from the present invention in that Jacques' handle 37 must slide distally in order for the lubricant to be pushed distally from the reservoir. Accordingly, the rod associated with this handle does not appear to be axially fixable. Moreover, since axially fixing the handle/rod combination would prevent further distal movement of the piston cups 16/17 and so prevent cement movement into the injection chamber, Jacques teaches away from the present invention.

Respecting Stampers, the rod portion of handle 18 / rod 15 combination of the Stampers device appears to extend fully through the reservoir, and appears to act merely as a centering piece for the spring. Accordingly, the rod of the Stampers device is not axially retractable.

In contrast, the shaft component of the present invention is both axially retractable and axially fixable. This feature allows the shaft to first be retracted (thereby compressing a spring attached thereto and creating a reservoir working space) and then fixed. Subsequent release of the spring by the shaft (for example, by rotation) allows the spring to exert force against the reservoir piston and cement. This advantage is not taught, but rather is taught away from, by the cited art.

Amended claim 55 recites a radially movable mixing element housed within the reservoir, such as a ball mixer. As discussed above, neither Jacques nor Stamper disclose any mixing element components in their devices. This silence is not surprising in light of the fact that lubricants are typically placed into the gun in their final form, thereby obviating any need to mix precursor components.

Applicant notes that Draenert reports a mixing vessel described in DE-A-17 66 334, having a ball separating the vessel into two chambers which can be pressed through to move freely as a stirring means in one of the two chambers. Draenert further discourages using such a ball when mixing bone cements:

While this principle may be applied in dental amalgams, it is not suitable for mixing bone cements, as the ball can not be removed from the curing bone cement and the moving ball results in laminations of the increasingly highly viscous bone cements. Therefore, with this principle it is not possible to achieve uniformly mixed bone cements. (Col. 2, lines 13-20).

Accordingly, Applicants take the position that the reference cited by Draenert is not combinable with Draenert because Draenert discourages its combination. Applicants have submitted herewith an Information Disclosure Statement disclosing US Patent No. 3,796,303 ("Allet-Coche"), which Applicants believe to be the US patent corresponding to DE-A-17 66 334.

Amended claim 59 recites a check valve having a slitted sheet. This claim also recites a flow restrictor having a slitted sheet and so is patentable for the same reasons provided in the discussion of claim 34.

Amended claim 79 recites a device having both an injection piston operable as an inlet check valve, and a flow restrictor having a slitted sheet and so is patentable for the same reasons provided in the discussion of claim 34.

Respecting Jacques, Jacques discloses a discharge check valve having a spring. Jacques does not teach or suggest a discharge check valve have a slitted sheet.

Respecting Stampers, Stampers discloses an inlet check valve comprising a freely moving ball:

In operation, retraction of the piston from the piston cavity creates a vacuum that simultaneously acts to open the inlet check valve and close

the discharge check valve; thus lubricant is drawn into the piston cavity
(col. 1, lines 36-40)

Thus, Stampers does not disclose an injection piston operable as an inlet check
valve.


Amended claim 82 recites an O-ring present in the injection chamber, and so is
patentable for the reasons discussed above in claim 7.

Respecting claim 100, Applicants note that the claimed invention recites injecting
bone cement into a vertebral body from a device having both a reservoir and an injection
chamber. None of the cited references discloses injecting bone cement into a vertebral
body. Therefore, the cited references can not be combined to produce the claimed
invention. Moreover, none of the prior art devices used in vertebroplasty comprised both
reservoirs and injection chambers. Rather, these vertebroplasty devices were single barrel
devices that could not provide the small, discrete injections desirable for controlling
injection volume in vertebroplasty procedures.

In addition, Applicants respectfully request that Applicants be provided with a
two month extensions of time for response, and charge any fees which may be due to
Deposit Account No. 10-0750, but do not include any payment of issue fees.

Should there be any remaining or further questions, the Examiner is requested to
place contact the undersigned directly.

Respectfully submitted,



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